DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

95P-0214

AUG 29 1997

Ms. Eleanor Sherman
Technowipe, Inc.
283 Murray Avenue
Larchmont, New York 10538-1604

Dear Ms. Sherman:

This letter officially responds to your citizen petition, dated July 11, 1995, regarding cleaning and disinfection of mammography equipment. As you know from our many conversations on this issue, FDA agrees with the general intent of your petition and, accordingly, has taken a number of actions to address the issue you raise -- i.e., assuring that manufacturers provide adequate information on how mammography equipment should be disinfected between patients. These actions include the following:

- Issuance of guidance on labeling reusable medical devices for reprocessing in health care facilities.

- Inclusion of requirements in the proposed quality standards for mammography equipment that facilities establish, adhere to, and document their compliance with a system of infection control; and that each facility's system adhere to infection control recommendations provided by the manufacturer(s) of the mammography equipment, or, if such recommendations are not available, each facility's system adhere to generally accepted guidance on infection control until such recommendations become available.

- Dissemination of information on this important issue in an article entitled, "Infection Control for Mammography Equipment," in the winter 1997 issue of Mammography Matters.

- Discussion of the general issue of disinfection of x-ray equipment, including mammography equipment, at the last annual meeting of the Radiological Society of North America (RSNA).

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I know that you already have copies of the above mentioned documents and that you attended the RSNA meeting.

Although the staff at the Centers for Disease Control and Prevention (CDC) have advised FDA that there have been no reported cases of transmission of human immunodeficiency virus (HIV), hepatitis B virus (HBV), or hepatitis C virus (HCV) to examinees or health care workers from the over 25 million mammograms performed each year, we agree it is important that appropriate infection control precautions are taken with respect to mammography equipment, and we believe that the actions FDA has taken address that issue. We appreciate the information you have provided the Agency on this important public health issue.

Sincerely yours,

Elizabeth D. Jacobson

Elizabeth D. Jacobson, Ph.D.
Deputy Director for Science
Center for Devices and
Radiological Health